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**IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN**

**Stanley H. Kremen,
Attorney at Law
4 Lenape Lane
East Brunswick, New Jersey 08816
(732) 593-7294
Attorney for the Plaintiff**

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender
neutral fictitious names, and ABC
CORPORATION 1 through 10 (fictitious
names).

Defendants.

CIVIL ACTION No. 2:21-cv-10312-SJM-RSW

**PLAINTIFF/COUNTERCLAIM DEFENDANT TRUTEK CORP.'S
ANSWER TO COUNTERCLAIMS AND AFFIRMATIVE DEFENSES**

Plaintiff/Counterclaim Defendant, Trutek Corp. ("Plaintiff" or "Trutek") by and through its undersigned counsel, submit the following Answers and Affirmative Defenses to Defendant/Counterclaim Plaintiff BlueWillow Biologics, Inc. ("Defendant" or "BlueWillow") Counterclaims.

TRUTEK'S ANSWER TO COUNTERCLAIMS¹

PARTIES

1. Plaintiff/Counterclaim Defendant Trutek Corp. admits that it is a corporation of the

¹ TRUTEK repeats the headings contained in the Counterclaims for reference only and their inclusion herein should not be interpreted as any admission or acquiescence as to the statements contained herein.

1 State of New Jersey, with principal offices at 281 East Main Street, Somerville,
2 New Jersey 08876.

3 2. On information and belief, Defendant/Counterclaim Plaintiff BlueWillow Biologics,
4 Inc. is a corporation of the State of Delaware with a place of business at 2311
5 Green Road, Suite A, Ann Arbor, Michigan 48105.

6 **JURISDICTION AND VENUE**

7 3. Trutek admits that this Court has subject matter jurisdiction over BlueWillow's
8 Counter-Complaint and Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a),
9 2201, and 2202.

10 4. Trutek admits that an actual case or controversy exists concerning infringement of
11 U.S. Patent No. 8,163,802 ("the '802 Patent") by BlueWillow, but denies the
12 existence of a case or controversy concerning invalidity of the '802 Patent as
13 insufficient facts were alleged by BlueWillow to support its allegations of invalidity.

14 5. Trutek admits that personal jurisdiction and venue are proper in this District
15 pursuant to 28 U.S.C. §§ 1391 and 1400(b).

16 **STATUS OF COUNTERCLAIMS**

17 6. In response to Defendant's Counterclaims, Plaintiff filed a Motion to Dismiss said
18 Counterclaims under Fed. R. Civ. P. 12(b)(6) on June 4, 2021 (ECF 11). In its
19 order of October 5, 2021 (ECF 15), the Court granted Plaintiff's motion dismissing
20 Count I (*viz.*, "declaratory Judgment that BlueWillow does not infringe the '802
21 Patent"), but denied Plaintiffs Motion regarding Count II ("declaratory judgment of
22 invalidity of the '802 Patent"). The Court further ordered Plaintiff to "answer the
23 Counterclaims no later than October 27, 2021."

24 7. The dismissal of Count I eliminates the requirement for Plaintiff to answer that
25 count.

26 **FACTUAL BACKGROUND**

27 8. *BlueWillow is a clinical-stage biopharmaceutical company focused on developing*
28 *a new generation of safe and effective intranasal vaccines for challenging*

1 *respiratory infections, sexually transmitted diseases, and food allergies.*

2 **ANSWER:** Trutek lacks knowledge or information sufficient to form a belief about
3 the truth of the allegations contained in Paragraph 6 of Defendant's Counter-
4 Complaint and therefore denies them.

- 5 9. *BlueWillow also developed and sold NanoBio[®] Protect, an over-the-counter nasal*
6 *antiseptic that uses BlueWillow's proprietary nanotechnology to deliver*
7 *benzalkonium chloride (BZK), a common skin antiseptic that has been used in*
8 *over-the-counter products for more than 75 years.*

9 **ANSWER:** Trutek notes BlueWillow's admission that it developed and sold
10 NanoBio[®] Protect and that it contains benzalkonium chloride, but it lacks
11 knowledge or information sufficient to form a belief about the truth of any or all
12 other allegations contained in Paragraph 7 of Defendant's Counter-Complaint and
13 therefore denies them.

- 14 10. *On February 10, 2021, Trutek filed suit alleging one count of patent infringement*
15 *of the '802 Patent against BlueWillow.*

16 **ANSWER:** Trutek admits the allegations contained in Paragraph 8 of Defendant's
17 Counter-Complaint.

- 18 11. *Trutek's Complaint alleges that BlueWillow's NanoBio[®] Protect products directly*
19 *infringe at "least claims 1, 2, and 7 of the ['802] Patent because the [NanoBio[®]*
20 *Protect] products possess an electrostatic charge when applied to a person's*
21 *nasal passages, and they use benzalkonium chloride as a biocide."*

22 **ANSWER:** Trutek admits that Count 1 of its Complaint alleges that "Defendants
23 infringe at least claims 1, 2, and 7 of the '802 Patent because the NANO BIO
24 products possess an electrostatic charge when applied to a person's nasal
25 passages, and they use benzalkonium chloride as a biocide." However, the
26 quotation attributed to Trutek by Defendant in Paragraph 9 is incorrect, and the
27 allegations contained therein are therefore denied.
28

12. *The '802 patent is invalid and has not been and is not infringed by BlueWillow, directly (either literally or under the doctrine of equivalents), indirectly, contributorily, or by inducement.*

ANSWER: Trutek denies Defendant's allegations contained in Paragraph 10 of its Counter-Complaint.

**COUNT II
DECLARATORY JUDGMENT OF INVALIDITY
OF THE '802 PATENT**

13. Trutek incorporates and re-alleges its answers to Paragraphs 1 through 12 of Defendant's Counter-Complaint as if fully set forth herein.

14. *All claims of the '802 Patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and 112.*

ANSWER: Trutek denies the allegations contained in Paragraph 19 of Defendant's Counter-Complaint. Further, Defendant failed to provide a basis for invalidity of the '802 Patent under 35 U.S.C. §§ 101, 102, 103, and/or 112.

15. *For example, at least the following prior art references render each claim of the '802 Patent invalid under 35 U.S.C. § 102 and/or § 103; U.S. Patent No. 6,559,189; U.S. Patent No. 6,506,803; U.S. Patent No. 10,138,279; U.S. Published Application No. 2006/0163149; U.S. Published Application No. 2004/0071757; and U.S. Patent No. 5,468,488.*

ANSWER: Trutek denies the allegations contained in Paragraph 20 of Defendant's Counter-Complaint. Further, while Defendant cited four patents and two patent application publications to support its claims in Paragraph 20 of its Counter-Complaint, Defendant failed to provide any reasoning for invalidating the '802 Patent under 35 U.S.C. § 102 and/or § 103. Plaintiff denies that claims of the '802 Patent are anticipated by any of the prior art references cited in Paragraph 20 of Defendant's Counter-Complaint under 35 U.S.C. § 102. Plaintiff further denies that the claims of the '802 Patent are unpatentable under 35 U.S.C.

1 § 103 over any one or a combination of two or more of the prior art references
2 cited in Paragraph 20 of Defendant's Counter-Complaint.

3 16. *There is a substantial controversy between Trutek and BlueWillow about the*
4 *invalidity of the '802 Patent by virtue of Trutek's claims of infringement by*
5 *BlueWillow that is of such immediacy and existence as to warrant a declaratory*
6 *judgment.*

7 **ANSWER:** Trutek denies the allegation contained in Paragraph 21 of
8 Defendant's Counter-Complaint. Defendant failed to provide any basis to even
9 form a *prima facie* case for invalidity of the '802 Patent other than a mere citation
10 of prior art references. Defendant alleged that the '802 Patent is invalid in
11 Paragraph 19 citing various sections of the federal patent statute (*i.e.*, Title 35 of
12 the United States Code). Yet, Defendant fails to state how the '802 Patent is
13 invalid for violation of its sections *supra*. Further, Defendant alleged in Paragraph
14 20 of its Counter-Complaint that the '802 Patent is invalid as anticipated (under 35
15 U.S.C. § 102) by the cited prior art or is obvious (under 35 U.S.C. § 103) over the
16 cited prior art without stating whether it is anticipated by or obvious over the cited
17 prior art references. Defendant provided no basis for its claims of anticipation and
18 obviousness other than a mere citation of prior art references. Furthermore, the
19 standard for establishing patent invalidity must be by clear and convincing
20 evidence. Other than making a blanket statement of patent invalidity by
21 BlueWillow in Count II of its Counter-Complaint, Defendant presents no basis of
22 such immediacy and existence as to warrant a declaratory judgment of patent
23 invalidity by this Court. Defendant failed to present a *prima facie* argument for its
24 claim of patent invalidity.

25 17. *Trutek's assertions of infringement of invalid claims of the '802 Patent, among*
26 *other things, has directly and proximately injured BlueWillow and continues to*
27 *injure BlueWillow.*

28 **ANSWER:** Trutek denies that any claim of the '802 is invalid. Moreover, Trutek

1 lacks knowledge or information sufficient to form a belief about the truth of the
2 remaining allegations contained in Paragraph 22 of Defendant's Counter-
3 Complaint and therefore denies them.

- 4 18. *BlueWillow's injury would likely be redressed by a finding that the claims of the*
5 *'802 Patent are invalid.*

6 **ANSWER:** Trutek lacks knowledge or information sufficient to form a belief about
7 the truth of the allegations contained in Paragraph 23 of Defendant's Counter-
8 Complaint and therefore denies them.

- 9 19. *BlueWillow is entitled to a declaratory judgment that the claims of the '802 Patent*
10 *are invalid.*

11 **ANSWER:** Trutek denies the allegation contained in Paragraph 24 of
12 Defendant's Counter-Complaint.

13 **PLAINTIFF/COUNTER-DEFENDANT AFFIRMATIVE DEFENSES**

- 14 20. Trutek asserts the following Affirmative Defenses, and it asserts all affirmative
15 defenses set forth in Fed. R. Civ. P. 8(c) and 12(b), under the patent laws of the
16 United States, and any other defenses, at law or in equity, that may now exist or
17 in the future be valid based on discovery and further investigation in this action.
18 No allegation of a defense is an admission regarding the Parties' respective
19 burden of proof.

20 **FIRST AFFIRMATIVE DEFENSE**
21 **THE '802 PATENT IS PRESUMED VALID;**
22 **EACH CLAIM IS PRESUMED VALID INDEPENDENTLY OF OTHER CLAIMS**

- 23 21. 35 U.S.C. § 282(a) establishes a presumption of validity of the '802 Patent. The
24 Statute also establishes a presumption of validity of each of the claims of the '802
25 Patent independently of the validity of the other claims. Further, it establishes that
26 all dependent claims are presumed valid even though dependent upon an invalid
27 claim. Finally, it establishes that the "burden of establishing invalidity of a patent
28 or any claim thereof shall rest on the party asserting such invalidity."

22. The allegations contained in the Counter-Complaint, or any purported cause of action therein, fail to state any facts to rebut the presumption of validity of the '802 Patent, nor have they stated any factual basis to establish invalidity of the '802 Patent.

23. The allegations contained in the Counter-Complaint fail to establish a *prima facie* case for invalidity of the '802 Patent.

**SECOND AFFIRMATIVE DEFENSE
PRESUMPTION OF PATENT VALIDITY
MUST BE OVERCOME BY CLEAR AND CONVINCING EVIDENCE**

24. According to a ruling by the United States Supreme Court, 35 U.S.C. § 282 establishes a presumption of patent validity that an alleged patent infringer must overcome by clear and convincing evidence in all circumstances.

25. The allegations contained in the Counter-Complaint, or any purported cause of action therein, fail to state any facts to rebut the presumption of validity of the '802 Patent by clear and convincing evidence.

RESERVATION OF RIGHTS AND OTHER DEFENSES

26. Trutek expressly reserves the right to add any additional defenses to counterclaims that discovery may reveal.

PRAYER FOR RELIEF

Wherefore, Plaintiff prays that in addition to the relief requested in its original complaint:

1. this Court issue a judgment specifically dismissing Defendant's Counterclaim of invalidity of the '802 Patent because Defendant failed to present sufficient facts to establish said Counterclaim according to a "clear and convincing" standard of proof;
2. this Court issue a judgment specifically dismissing Defendant's Counterclaim requesting a declaratory judgment of invalidity of the '802 Patent and denying Defendant's prayer for relief thereto because Defendant failed to establish a *prima facie* case for such relief;

- 1 3. this Court issue a judgment denying Defendant's prayer for awarding attorney's
- 2 fees because Defendant failed to provide sufficient reason for doing so;
- 3 4. this Court issue a judgment denying Defendant's prayer for awarding costs of suit
- 4 because Defendant failed to provide sufficient reason for doing so;
- 5 5. this Court provide such other, further, and additional relief that may be considered
- 6 just and equitable based on the facts and allegations contained in Plaintiff's
- 7 original Complaint or that arise in the course of proceedings.

8 Respectfully submitted,

9 Dated: October 18, 2021

s/ Stanley H. Kremen

Attorney for Plaintiff Trutek Corp.

4 Lenape Lane

East Brunswick, NJ 08816

Telephone: (732) 593-7294

Facsimile: (732) 312-5218

Email: *shk@shk-dplc.com*

CERTIFICATE OF ELECTRONIC SERVICE

I hereby certify that on October 20, 2021, I electronically filed this document, **PLAINTIFF/COUNTERCLAIM DEFENDANT TRUTEK CORP.'S ANSWER TO COUNTERCLAIMS AND AFFIRMATIVE DEFENSES** with the Clerk of the Court for the Eastern District of Michigan using the ECF System, which will send notification to the registered participants of the ECF System as listed on the Court's Notice of Electronic Filing.

s/ Stanley H. Kremen
Stanley H. Kremen,
Attorney for Plaintiff Trutek Corp.
4 Lenape Lane
East Brunswick, NJ 08816
Telephone: (732) 593-7294
Facsimile: (732) 312-5218
Email: *shk@shk-dplc.com*